K080538

# 510(k) Summary

JUL - 3 2008

# IDEAL LIFE Pod™ ILP 0001

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|---|---|
| Name of Device: | **IDEAL LIFE Pod™ Model ILP 0001** |
| Common Name: | Over the Counter Blood Glucose Test System |
| Classification Name: | 21 CFR 862.1345, Class II |
| Product Code: | NBW |
| Classification Panel: | Clinical Chemistry Devices Panel |
| Sponsor: | IDEAL LIFE INC.<br>110 Eglinton Ave., West, Ste. 303<br>Toronto, M4R 1A3<br>Ontario, CANADA |
| Contact: | Jason M. Goldberg |
| Tele: | 416.489.1494, Ext 200 |
| Fax: | 416.489.3009 |
| Date Prepared: | February 15, 2008 |

## A. LEGALLY MARKETED PREDICATE DEVICES

K984527, In Touch Diabetes Management Software, Lifescan, Inc.
K060504, IDEAL LIFE Pod, IDEAL LIFE INC.

## B. DEVICE DESCRIPTION

The IDEAL LIFE Pod is a simple, user-friendly wireless modem accessory that wirelessly receives data from IDEAL LIFE devices and transmits the data to the IDEAL LIFE website. The IDEAL LIFE database is updated securely with the user's information, which is available for review via secure Internet access. Using the Pod, an individual can more easily view and track their blood pressure, blood glucose, and/or body weight information.

## C. INTENDED USE

The IDEAL LIFE Pod™ receives data wirelessly from IDEAL LIFE devices to transmit over the Internet or common telephone lines from the user's home. The Pod is an optional accessory to IDEAL LIFE devices, including the GlucoManager™, the BP-Manager™ and/or the Body Manager™. The Pod is intended to aid people at home and health care professionals to review and evaluate historical blood glucose, weight and blood pressure test results, to support effective health care management.

The IDEAL LIFE Pod makes no interpretation, evaluation, medical judgment or recommendations for treatment. This device is not intended as a substitute for medical care.

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## D. SUBSTANTIAL EQUIVALENCE SUMMARY

The IDEAL LIFE Pod Model ILP 0001, Version 2, is substantially equivalent to the Intended Use of the In Touch Diabetes Management Software (K984527) and both the Intended Use and technology of the IDEAL LIFE Pod Model ILP 0001, Version 1 (K060504). Differences with the new Pod have been demonstrated not to affect safety or effectiveness of the device, using software design controls, V&V testing, and user testing of the device. The decision algorithm brings us to a determination of Substantial Equivalence, as defined in the Federal Food, Drug, and Cosmetic Act.

## E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the IDEAL LIFE Pod Model ILP 0001 and the predicate Pod are extremely similar, having the same software and hardware design and controls and basic functionality.

## F. TESTING

Hardware, software, and the manufacturing processes are the same as the predicate Pod. Software controls and validation and verification testing have demonstrated that the software changes do not affect device performance. Since the Pod is a wireless device, the radiofrequency interference and emissions have been tested and the Pod complies with appropriate FCC Standards. User testing and historical experience with the Pod have demonstrated that the Pod can be used in the intended setting.

## G. CONCLUSIONS

IDEAL LIFE INC. has demonstrated through its comparison of characteristics with the predicate devices and software and hardware testing, that the ILP Model 0001, Version 2 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ideal Life, Inc.
c/o Mandell Horwitz Consultants LLC
Diane Horwitz, Ph.D., Regulatory Affairs Consultant
2995 Steven Martin Drive
Fairfax, VA 22031

Re: k080538
Trade/Device Name: IDEAL LIFE Pod™, Model ILP 001
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: June 30, 2008
Received: June 30, 2008

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): **K080538**

Device Name: **IDEAL LIFE Pod™, Model ILP 0001**

Indication For Use:

The IDEAL LIFE Pod™ receives data wirelessly from IDEAL LIFE devices to transmit over the Internet or common telephone lines from the user's home. The Pod is an optional accessory to IDEAL LIFE devices, including the GlucoManager™, the BP-Manager™ and/or the Body Manager™. The Pod is intended to aid people at home and health care professionals to review and evaluate historical blood glucose, weight and blood pressure test results, to support effective health care management.

The IDEAL LIFE Pod makes no interpretation, evaluation, medical judgment or recommendations for treatment. This device is not intended as a substitute for medical care.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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